



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2014

Vadiswire Corporation
Mr. Edward Wulfman
President
339 Kirkland Way #G
Kirkland, WA, 98033

Re: K141218

Trade/Device Name: ZigiWire Mode2 Guidewire System, ZigiWire Mode3 Guidewire System
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Class: Class II
Product Code: DQX
Dated: November 20, 2014
Received: November 24, 2014

Dear Mr. Wulfman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

510(k) Number (if known)

K141218

Device Name

ZigiWire Mode2 Guidewire System

ZigiWire Mode3 Guidewire System

Indications for Use (Describe)

The ZigiWire Guidewire Systems facilitate placement and exchange of catheters and other instruments in the peripheral vasculature. The ZigiWire Guidewire Systems are not intended for use in the coronary arteries or neurovasculature.

Type of Use (Select one or both, as applicable)

 Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY**General Information:**

Date of Summary Preparation: May 09, 2014

Name and Address of Manufacturer: Vadiswire Corporation
339 Kirkland Way #G
Kirkland, WA 98033

Contact Person: Edward (Ted) Wulfman
President
Phone: 425-985-1570
Fax: 425-889-9201

Device Trade Names: ZigiWire Mode2 Guidewire System
ZigiWire Mode3 Guidewire System

Common Name: Wire, Guide, Catheter

Regulation Number: 21 CFR 870.1330

Regulation Name: Catheter guidewire

Regulatory Class: Class II

Classification Panel: Cardiovascular

Product Code: DQX

Performance Standards: Performance Standards do not currently exist for these devices. None are established under Section 514.

Device Description: The Vadiswire ZigiWire Mode2 and ZigiWire Mode3 Guidewire Systems are sterile guidewire systems designed to facilitate the placement of diagnostic catheters and sheaths in the peripheral vasculature. The individual guidewires used in the ZigiWire Systems consist of exchange length peripheral guidewires cleared under AdvanceCath (TechDevice) Corporation's 510(k) K053251. TechDevice Corporation manufactures the guidewires used in the ZigiWire Systems for Vadiswire, which are individually the same as several of the guidewires previously cleared under K053251.

The ZigiWire Systems consist of two models: one (ZigiWire Mode3) incorporates three individual exchange length peripheral guidewires, and the second (ZigiWire Mode2) incorporating two individual exchange length peripheral guidewires. The individual guidewires used in the system range from 0.014 – 0.022 inches in diameter and are standard Teflon-coated, stainless steel guidewires with flexible radiopaque tips. Each ZigiWire System is provided with the individual guidewires in an all straight tip shape, or with all guidewires in the J-tip shape. The ZigiWire Systems are also provided with accessories which are intended to assist in inserting the guidewires into diagnostic catheters. These accessories consist of a wire introducer, which loosely holds the individual guidewires and helps to guide them into the hub of a catheter, a handle to separate the wires prior to use, and wire torquers for each wire. The handle incorporates a side port to enable flushing the introducer with the guidewires in place.

Indications for Use: The ZigiWire Guidewire Systems facilitate placement and exchange of catheters and other instruments in the peripheral vasculature. The ZigiWire Guidewire Systems are not intended for use in the coronary arteries or neurovasculature.

Predicate Devices: Vadiswire Corporation cites the following devices as the predicate devices for the substantial equivalence basis.

Predicate Devices	Predicate 510(k)
AdvanceCath (TechDevice) Guidewire	K053251
Amplatz Super Stiff Guidewire	K942382

Testing Summary: To demonstrate substantial equivalence of the subject ZigiWire Guidewire Systems to the predicate devices, the technological and performance characteristics were evaluated by completion of the following testing:

- Bond Testing
- Aseptic Removal from Pouch
- Wire Removal from Handle
- Wire Handle Hold and Release of Guidewire
- Introducer Flushing
- Manual Tip Forming
- Wire Placement in Simulated Use
- Catheter Compatibility
- Steerability

- Deliverability of Guiding Catheter or Sheath
- Guidewire Removal
- Tip Flexibility

The results from these tests:

- demonstrate that the technological and performance characteristics of the subject ZigiWire Guidewire Systems are comparable to the predicate devices,
- support the safety and effectiveness of the devices that are the subject of this 510(k), and
- ensure the subject devices can perform in a manner equivalent to the predicate devices with the identical intended use.

Conclusion (Statement of Equivalence): The data and information presented within this submission (including *in vitro* bench testing) and the similarities between the subject and predicate devices support a determination of substantial equivalence, and therefore market clearance of the subject ZigiWire Guidewire Systems through this 510(k) Premarket Notification.